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DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY
GLAXOSMITHKLINE
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

MULLEN, THOMAS J

ART UNIT PAPER NUMBER

2632

DATE MAILED: 10/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,760

Applicant(s)

ANDERSON ET AL.

Examiner

Thomas J. Mullen, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: .

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 450 (page 15, lines 26, 29 and 30). A proposed drawing correction or corrected drawings--or removal of the numeral 450 from the specification--are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. Headings are required in the specification, per 37 CFR 1.77(c).
3. It is noted that the final paragraph of the specification (starting on page 19, line 6) refers to possible "subsequent application(s)" (such as a continuation, CIP, etc.). Applicant's right to file such an application is not in dispute; however, with regard to the statement that the "claims" of such an application "may include...one or more of the following claims", it should be noted that if claims are present in a continuation/CIP application which are the same as, or not patentably distinct from, corresponding claims in this application, such claims would be subject to a double patenting rejection (either under 35 U.S.C. 101 or non-statutory obviousness-type double patenting).
4. The disclosure is objected to because of the following informalities:
 - page 1, lines 12, 15, 18 and 23, and page 2, lines 15 and 33, it appears that "regime" (total of six occurrences) should be --regimen--;
 - page 12, lines 7, 10, 13, 17, 20, 23 and 26, the period following each numeral in the expressions "Figure 1.", "Figure 2.", etc. (total of eight occurrences) should be deleted;
 - page 12, lines 13 and 17, both Fig. 3 and Fig. 5 are described as a "third" system (embodiment) of the invention, but it appears that these figures correspond to different embodiments (as discussed later in the specification);
 - page 13, line 29, the period at the end of the first occurrence of "Figure 2." should be deleted;
 - page 13, line 29, it appears that the second occurrence of "Figure 2" should be --Figure 1--;
 - page 14, line 21, it appears that ".e." should be --i.e.--;

page 14, line 29, it appears that the first occurrence of "by" should be deleted;
page 15, lines 22 and 32, the period at the end of each occurrence of "Figure 5." should be deleted;
page 16, line 7, the period at the end of "Figure 6." should be deleted;
page 17, line 27, it appears that "s the" should be --as the--;
in the paragraph overlapping pages 17-18, there are fourteen occurrences of "eg" which should be --e.g.-- or --e.g.,--; and
page 18, line 30, "eg" should be --e.g.-- or --e.g.,--.
Appropriate correction is required.

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following elements must be shown or the feature(s) canceled from the claim(s):

"transmitter" AND the "communicator" (recited as separate elements in each of claims 1 and 50--see paragraph 7 below);

"coupling mechanism" (claim 50--see paragraph 7 below);

"gateway" (claim 5);

"embedded network server" (claim 6);

"cellular phone or pager" (claim 8);

"emergency assistance provider" (claim 18);

"research establishment" (claim 20);

"local data store" in the form of a "personal computer or set-top box" (claims 22-24);

"predictive algorithm or look-up table" (claims 28 and 46);

"selector" (claims 30-32);

"geographic positioning system" (claim 34);

"breath-movable element" (claims 36-37);

"actuator" (claims 45 and 49); and

"aerosol valve" (claim 47).

No new matter should be entered.

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A proposed drawing correction or corrected drawings--or removal of these elements from the claims--are required in reply to the Office action to avoid abandonment of the application.

The objection to the drawings will not be held in abeyance.

In general, many of the elements recited in the claims are only discussed in the portion of the specification which would correspond to the "Summary of the Invention" (i.e., from page 2, line 20 to page 12, line 2), and not in what would correspond to the "Description of the Preferred Embodiment(s)" (starting on page 12, line 26); thus, the above-listed elements do not have reference numerals associated therewith in the specification, such that they do not have any apparent equivalence in the drawings. The extent to which correspondence exists between the latter part of the specification and the former part, as to a clear description of the claimed invention, is insufficient for one to draw a parallel between the above-listed elements in the claims and the elements which are identified by reference numerals in the drawings.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In each of claims 1 and 50, it is unclear based on the disclosure (i.e., specification and drawings) which particular operative component(s), as shown in the drawings, is/are intended to constitute at least one specific embodiment of each of the following claimed elements-- "electronic data management system", the "transmitter", and the "communicator" --and therefore the claims fail to particularly point out and distinctly claim the subject matter regarded as the invention:

Regarding the "electronic data management system", the following points are noted regarding what is disclosed, with reference to the specification and drawings:

as to Fig. 1, it is stated on page 13, lines 9-11 that the electronic data management system is "within the housing" 10 and is in the form of an "integrated circuit" which is "not visible", Fig. 1 merely showing a "communications transceiver" 40 and the "data management" portion of the

system being merely described in terms of "user access" and "menu choices" (page 13, lines 11-14) rather than its specific components;

as to Fig. 2, element 140 is described as an "electronic data management and communications system" and as a "chip" (page 13, last 2 lines and page 14, first 2 lines), but this element appears in Fig. 2 in roughly the same form as "communications transceiver" 40 of Fig. 1 (which presumably does not include all of the elements associated with the "data management system" per se);

also in Fig. 2, there is a "palmtop computer" 170 physically separated from dispenser housing 110, but apparently not containing an "electronic data management system" (it is unclear from the disclosure whether the "patient", or some other party, carries/uses the palmtop computer);

as to Figs. 3-5, blocks 240 and 340 are each labeled "electronic data management system" and block 440 is labeled "patient data manager", but the specification and drawings do not show or describe any operative component(s) thereof, i.e. it is not apparent what element(s) within (or on the exterior of) housing 10 of Fig. 1 or housing 110 of Fig. 2, or which of the components shown in Fig. 7 (see below), correspond to the "system" 240, 340 or 440; and

as to Fig. 7, block 610 is described as a "patient electronic data manager", which does include a CPU (621), RAM and ROM (622,623), data storage device (625,626,628) and communication port and link (640,642), among other elements--however, the correspondence between the elements shown in Fig. 7 and each of the elements recited in claims 1 and 50 is unclear (note the other claimed elements discussed below, i.e. the "transmitter", "communicator" and "coupling mechanism").

Therefore, the disclosure as a whole fails to provide a cohesive teaching of at least one specific embodiment of the claimed "electronic data management system".

Regarding the "transmitter" and "communicator", it appears from the disclosed invention that the "communicator" as recited in claims 1 and 50 carries out all the necessary "communication" between the dispenser housing (10 in Fig. 1 and 110 in Fig. 2) and the remote "network" elements, whereby it is not apparent what additional function is provided by the "transmitter" (in this respect, it is unclear what is meant by the recitation of a transmitted signal "relating to the data or the outcome of an operation on the data", as in claims 1 and 50). Also, it

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is unclear from the way claims 1 and 50 are written whether the "transmitter" is considered part of the "electronic data management system", or is some distinct element. Therefore, the disclosure as a whole fails to provide a cohesive teaching of at least one specific embodiment of the claimed "transmitter", as an element which is structurally and functionally distinguished from the claimed "communicator".

Further, it is unclear which particular element (or group of elements), as shown in the drawings, are intended to constitute the "coupling mechanism" of claim 50; for one thing, it is unclear if the "coupling" refers to an electronic coupling (i.e., for the communication of signals) or a mere physical coupling. For example, Fig. 7 includes a sensor 615 which may detect "actuation" of a drug delivery system, which sensor communicates with patient data manager 610; on the other hand, a "snap-fit module" is mentioned at page 3, line 18 and a "snap-in module" is mentioned at page 11, line 26, but such modules are not shown (or at least not identified) in the drawings. It is unclear what is contemplated by the claimed "coupling mechanism" between the communicator and the dispenser.

In claims 1 and 50, it is unclear whether the "data" (see claim 1, line 5 and claim 50, line 3) has anything to do with the dispensing of a "medicament", i.e. it is unclear from the manner in which the claims are written whether the "data management system" (or "data communicator") and the "medicament dispenser" are functionally interrelated.

At the end of claim 14, it is unclear what element(s), entities, etc. is/are meant by "thereto".

8. Claim 9 is objected to under 37 CFR 1.75(a) for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9, "the second communications device" lacks antecedent basis (note the dependency of the claim).

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1-2, 4, 12 and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by any of Blomquist (US 5,338,157, cited by applicant), Mishelevich et al (US 5,363,842), Davis et al (US 5,544,661) or Wolf (US 5,809,997), or in the alternative under 35 U.S.C. 102(e) as being anticipated by McKinnon et al (US 6,202,642).

Note in Figs. 1, 1A and 2 of Blomquist, medicament container/dispenser (40,64); "electronic data management system" including memory/microprocessor 41 (col. 6, lines 52-55) and transmitter/communicator 48 (col. 8, lines 26-39); and network computer system (80,86,etc in Fig. 2--col. 14, line 46 to col. 15, line 14). Blomquist teaches that communication from the electronic data management system to the network may be "wireless", e.g. cellular, satellite or microwave links (col. 8, lines 35-36). Regarding the "coupling mechanism" of claim 50, note "connection structure" 50 between the medicament dispenser and the data communicator (col. 8, lines 26-28).

Note in Mishelevich et al, medicament container/dispenser 100; "electronic data management system" (Fig. 4) including memory ("ROM" and "RAM"), "microprocessor" and transmitter/communicator ("I/O interface" in Fig. 4, and "data communication means" 221 in Figs. 2A-2B--col. 6, lines 30-32 and col. 7, line 65 to col. 8, line 2); and network computer system ("computer based clinical workstation"--col. 6, lines 30-31 and col. 7, lines 67-68). Mishelevich et al teaches that communication from the electronic data management system to the network may be "wireless", e.g. by means of a "compact transceiver means" through a "radiofrequency communication channel" (col. 6, lines 35-39). Regarding the "coupling mechanism" of claim 50, note that the "data communicator" (including integrated circuit 220 and data communication means 221) is built into the dispenser housing 100 in Figs. 1, 2A and 2B.

Note in Figs. 1-2 of Davis et al, therapeutic apparatus 207 (in the embodiment shown, element 207 is described as a "defibrillation unit"; however, Davis et al further teaches that in an alternate embodiment the therapeutic device may be a "drug infusion device"--see the last line of

the Abstract and col. 8, lines 56-61--whereby Davis et al implicitly teaches a "medicament container/dispenser"); "electronic data management system" (11) including memory/micro-processor 102 (col. 3, lines 2-3) and transmitter/communicator 509 (col. 3, lines 6-12); and network computer system (note elements 104B,105,106,etc in Fig. 1). The communication from the electronic data management system to the network includes a "cellular" link (509,104B) which is a form of "wireless" communication. Regarding the "coupling mechanism" of claim 50, as shown in Figs. 1-2 the "data communicator" 11 (via control logic 109) is coupled to the element 207 which is implicitly taught to be "medicament container/dispenser" as discussed above.

Note in Wolf, medicament container/dispenser (120,215); "electronic data management system" 400 (see Figs. 4-6 and 8) including memory 860 ("RAM"), "microprocessor" 605 and transmitter/communicator (note "communication connector" 415 in Figs. 4 and 8); and network computer system (see e.g. Figs. 10 and 20 and col. 22, lines 27-53). Wolf teaches that communication from the electronic data management system to the network may be "wireless", note "wireless data communications" infrared transmitter and receiver (1450,1460) in Figs. 14 and 20. Regarding the "coupling mechanism" of claim 50, as best shown in Fig. 5 the "data communicator" 400 is built into the dispenser housing 120.

Note in McKinnon et al, medicament container/dispenser (100,500); "electronic data management system" 116 (see Figs. 1-2 and 4) including "memory" 432, microprocessor 428 and transmitter/communicator 400 ("IR port" in Fig. 4--see col. 4, lines 1-4); and network computer system (note elements 304,308,312 in Fig. 3, and col. 4, lines 4-17). McKinnon et al teaches that communication from the electronic data management system to the network may be "wireless" (col. 3, line 46 to col. 4, line 4). Regarding the "coupling mechanism" of claim 50, as best shown in Figs. 1-2 the "data communicator" 116 is built into the dispenser housing 100.

Regarding claim 2, in each reference the communication between the "network computer system" and the "electronic data management system" involves "two-way transfer of data".

Regarding claim 4, in each reference it is taught that the "wireless" transmission to/from the "communicator" may be in the form of at least one of "radiofrequency" or "optical" signals.

Regarding claim 12, since each reference teaches communicating data over a "network" (which implicitly has two or more entities connected thereto), it appears to be inherent that the

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party which receives a communication from the "electronic data management system" has some form of user-specified network "address" such that the communication is received only by the appropriate party.

11. Claims 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Blomquist or Davis et al.

Blomquist and Davis et al specifically teach that communication with the "network computer system" ^{is} via a telecommunications device, in particular a "cellular phone" (note col. 8, line 35 in Blomquist, and element 509 in Davis et al).

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12. Claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolf.

Note in Fig. 20 of Wolf, "docking station" 2030 which contains its own memory storage capability (col. 22, line 19); as discussed above, Wolf uses an infrared transmitter and receiver (1450,1460) to communicate between the medication dispenser/communication unit 100 and the network (via the docking station, i.e. the docking station 2030 is a "local data store" in the form of a "set-top box").

13. Claims 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by any of Blomquist, Mishelevich et al or Davis et al, or in the alternative under 35 U.S.C. 102(e) as being anticipated by McKinnon et al.

Each of Blomquist, Mishelevich et al and McKinnon et al disclose a keypad in association with the electronic data management system, note 44 in Blomquist; 104 in Mishelevich et al; and 436 in McKinnon et al. Davis et al discloses a "data input system" in the form of a "voice recognition interface" (111,202A,202B in Fig. 1; 202,202A,202B in Fig. 2).

14. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by any of Blomquist, Mishelevich et al or Wolf, or in the alternative under 35 U.S.C. 102(e) as being anticipated by McKinnon et al.

Note display 46 in Blomquist; display 108 in Mishelevich et al; display 890 (Fig. 8) or 1135 (Fig. 11) in Wolf; and display 440 in McKinnon et al.

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15. Claims 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Mishelevich et al, or in the alternative under 35 U.S.C. 102(e) as being anticipated by McKinnon et al.

Note in Mishelevich et al, Fig. 6A; col. 5, lines 41-57; and col. 6, lines 40-45.

Mishelevich et al teaches that a physician at the "clinical (remote) workstation" may "adjust" or "reprogram" the prescription data in the patient's medicament container/ dispenser 100, so as to "alter the dosage"; i.e., Mishelevich et al inherently provides a "selector" for the medicament amount to be dispensed, which is "manually operable" (by the physician) and whose commands to the electronic data management system may be communicated via "transmitter" (i.e., via the "radiofrequency communication channel").

Note in McKinnon et al, Fig. 28 and col. 14, lines 1-21. The display present at the physician's workstation (308 in Fig. 3) includes "Dosage" information, in particular the "number of doses, puffs per dose and timing of doses", which can be "programmed into the medicine dispensing (apparatus) 100" by the physician; i.e., McKinnon et al inherently provides a "selector" for the medicament amount to be dispensed, which is "manually operable" (by the physician) and whose commands to the electronic data management system may be communicated via "transmitter" (i.e., via the "infrared transceivers").

16. Claims 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by either Mishelevich et al or Wolf, or in the alternative under 35 U.S.C. 102(e) as being anticipated by McKinnon et al.

Regarding claim 33, each of Mishelevich et al , Wolf and McKinnon et al teaches detecting the dispensing of the medicament (see the Abstract in Mishelevich et al and Wolf, and col. 9, lines 41-59 in McKinnon et al), and implicitly stores and communicates dispensing occurrences as "data".

Regarding claim 35, each of Mishelevich et al, Wolf and McKinnon et al uses a "data communicator" in the environment of an "inhaler" or breath-flow device (see the Abstract and Fig. 1 in each reference). Therefore, each of Mishelevich, Wolf and McKinnon et al implicitly includes a "breath" sensor.

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17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 3, 5, 6, 9-11, 13-21 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Blomquist, Mishelevich et al, Davis et al, Wolf or McKinnon et al.

The examiner takes Official notice that the various features recited in claims 3, 5, 6, 9-11 and 13-21 would have been obvious to those skilled in the art of communications and control systems for communicating data pertaining to patients or other medical concerns over a "network"; i.e., the presence of "gateways" and/or "servers" in the network, the network being either "public" or "private" access, the use of "spread spectrum" signals, the "encrypting" of data, and the particular types of network "addresses" and particular parties having accessibility to that "address", would have flowed logically from implementation of the system in any of Blomquist, Mishelevich et al, Davis et al, Wolf or McKinnon et al.

Regarding claim 34, the examiner takes Official notice that it is well known for doctors, hospitals or other responsible parties to provide a means for monitoring the whereabouts of patients, since patients sometimes wander away from a designated area and become lost and/or disoriented, depending on their age or their particular medical condition; therefore, it would have been obvious to one skilled in the art to incorporate a GPS device with the "electronic data management system" in any of Blomquist, Mishelevich et al, Davis et al, Wolf or McKinnon et al.

19. Claims 36-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Mishelevich, Wolf and McKinnon et al.

Where each of claims 36-49 depend, directly or indirectly, from claim 35 (discussed in paragraph 16 above), the examiner takes Official notice that the various features recited in claims 36-49 are either taught in at least one of Mishelevich, Wolf and McKinnon et al, or would have

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been obvious to those skilled in the art of communications and control systems for remote monitoring of patient "breath", since one skilled in the art would have recognized that the various recited means and processes for sensing breath, analyzing breath data, and "actuating" or "triggering" a particular type of dispensing mechanism are applicable to this environment.

20. Claims 28-29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

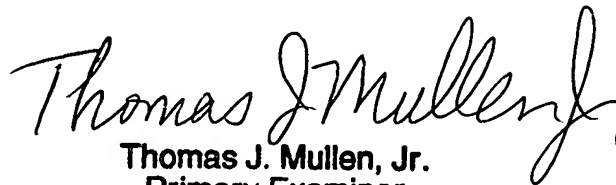
The remaining art cited by applicant is made of record. Steen, Worthington et al, Nohl et al and Stenzler (eff. date 8/29/00) are cited to further show the state of the art.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Mullen, Jr. whose telephone number is 703-305-4382. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 4 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Wu, can be reached on (703) 308-6730. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9313.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3900.

TJM


Thomas J. Mullen, Jr.
Primary Examiner
Art Unit 2632